Reply to Office Action of Mar. 5, 2008

Docket No.: 66307-328-7

REMARKS

By this Amendment the title has been amended to be more descriptive of the invention, the specification has been amended to include standard topic headings, claims 1-6 and 8-17 have been amended to improve their presentation, and new claims 24 and 25 have been added to further define the invention as defined in claim 1 (see specification at page 5, lines 4-6 and 20-24 and page 5, lines 4-8 and 20-23). Entry is requested.

A supplemental page 46 for this application containing an abstract of the disclosure is submitted herewith.

In the outstanding Office Action the examiner states that his restriction requirement (as set forth in the Office Action of October 26, 2007) has been made final, referencing Macauley (newly cited). The applicants Petition from this decision. The present application is directed to a discrete powder (claim 1) and a process for the preparation of a discrete powder (claim 7) as well as to various products incorporating the powders (claims 18 to 23). Macauley discloses a process for making a substantially dry free-flowing powder of microscopic discrete capsules which possess a shell or wall containing therein a marking fluid (col. 1, lines 20 to 20 and as shown in Figure 1). Contrary to the examiner's suggestion, Macauley does not disclose microscopic capsules containing an emulsion (col. 4, lines 35 to 55). Instead this patent discloses that the

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microscopic capsules are produced by first forming an emulsion. The continuous phase of the emulsion is the film-forming polymer which forms the shell of the capsule. The discontinuous phase forms the liquid center of the capsule. There is no disclosure of a powder containing an emulsion. If the polymer shell of the capsules of Macauley is compressed, or dissoluted, the marking liquid (discontinuous phase), not an emulsion, is released. Furthermore, this patent is silent on biliquid foams (see below for the difference between emulsions and biliquid foams). There is no disclosure in Macauley of a discrete powder as defined in claim 1. Groups II to VII are based upon this common novel and non-obvious feature.

The examiner's restriction requirement based on lack of unity should be overturned.

The examiner has suggested (top of page 3 of the Office Action) that this application is not entitled to priority from the original application filed in <u>Germany</u> on <u>3 August 2002</u>. However, the priority application was filed in <u>Great Britain</u> on 26 June 2002, and the present application is certainly entitled to this priority date as PCT/GB2003/002713 was filed within the required year.

The examiner has rejected claim 1 under 35 U.S.C. 112 because it is indefinite. This rejection is without merit. The applicant clearly discloses a powder formed of particles of a <u>biliquid</u> foam within a <u>polymer</u> matrix.

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The examiner has rejected claims 1, 2 and 4-6 under 35 U.S.C. 102(b) as being anticipated by Hiestand et al. This rejection is incorrect.

Hiestand et al. (U.S. 3,549,555) discloses a lipophilic-liquid-in-hydrophilic emulsion wherein the particles are coated with a coacervate and then hardened. There is no disclosure in this document of a biliquid foam.

Biliquid foams and emulsions are not the same. The Examiner will, of course, not need any explanation as to what is meant by an emulsion. This is a term commonly used in chemistry and covers, for example, an oil droplet suspended in an aqueous medium. The droplet is surrounded by a single layer of surfactant molecules which prevents coalescence with neighboring droplets.

A biliquid foam is rather different and is much more unusual. Biliquid foams were first discovered about thirty years ago. One way of understanding a biliquid foam is to regard it as being rather like a standard foam wherein the internal gaseous phase of the film is replaced by a liquid. Thus, in a standard biliquid foam, the dispersed phase usually exceeds 74% and may be as great as 98% of the total liquid volume. Thus, the internal phase makes up a significantly higher proportion of the total composition than in a standard emulsion. In the literature it has been proposed that the internal phase is surrounded by a double layer of surfactant molecules which prevent coalescence with neighboring droplets. If an emulsion is entrapped within a polymer matrix, when the

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polymer matrix dissolves and releases the droplets in the powder the emulsion will tend to coalesce. In contrast to this, if a biliquid foam is entrapped within a polymer matrix, when the polymer matrix dissolves and releases the droplets in the powder, the biliquid foam droplets remain as individual droplets. This is particularly useful for many applications, for example the controlled release of substances, and specifically drug release. It is therefore submitted that the examiner's rejection of claims 1, 2 and 4-6 as being anticipated by Hiestand et al. should be withdrawn.

The examiner has rejected claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Hiestand et al. in view of Macauley. This rejection is also incorrect.

Hiestand et al. (U.S. 3,549, 555) discloses a lipophilic-liquid-in-hydrophilic emulsion wherein the particles are coated with a coacervate and then hardened. Hiestand at al. is, however, silent on the use of biliquid foams.

The robustness and stability of biliquid foams in the discrete powder of the present invention provides a number of technical advantages over the emulsion dispersions described in Hiestand at al. In particular, in the powders of the present invention the biliquid foam droplets remain intact in the matrix powder.

Typically, compression processes used in generating tablets leads to a loss in the stability of droplets entrapped in a powder. However, the present inventors have surprisingly found that the stability of the

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entrapped biliquid foam enables the droplet size to be maintained during spray drying and in the discrete powder itself. The powder of the present invention may be compressed to form a tablet and even after compression, upon dissolution of the tablet in, for example, deionized water, the droplet size of the released biliquid foam remains unaffected (see page 32). This would not be expected with oil-in-water emulsions described in Hiestand et al. and is thought to be a unique characteristic of biliquid foams. This property allows the droplet size of the biliquid foam to remain essentially the same after entrapment and release, and is particularly important when the discrete powder is used, for example, in drug delivery systems (see page 5, lines 20 to 23).

There is nothing in Hiestand et al. to suggest that it would be possible, or advantageous, to incorporate biliquid foams into their powders. It is therefore submitted that the present invention is inventive over Hiestand at al. Furthermore, Macauley is silent on biliquid foams, it is therefore submitted that even if the teaching of these two documents were combined, the invention defined in claims 1-6 would not be suggested.

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Favorable reevaluation is requested.

All government fees can be charged to Deposit Account No. 04-2223.

Respectfully submitted,

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